November 21, 2017

Texas Medical Technologies, Inc.
% Mr. E.J. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K170914
Trade/Device Name: TXM Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 13, 2017
Received: October 16, 2017

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170914

Device Name
TXM Support Catheter

Indications for Use *(Describe)*
The TXM Support Catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TXM Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 5: 510(k) Summary

5.1 – Company Information & Contact Person

Company Name:	Texas Medical Technologies Inc.
Company Address:	9005 Montana Ave. Ste. A El Paso, Texas 79925
Telephone:	(915) 774-4321
Fax:	(915) 774-4323
Contact Person:	Cesar Rios, Quality Assurance & Regulatory Manager
Date Prepared:	02/28/2017

5.2 – Device Name & Classification

Proprietary Name:	TXM Support Catheter
Common Name:	Catheter, Support
Classification Name:	Catheter, Percutaneous
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Device Class:	II

5.3 – Predicate Device

Legally Marketed Substantially Equivalent Predicate Device

Proprietary Name:	TrailBlazer™ Support Catheter
Company Name:	ev3 Inc.
Common Name:	Catheter, Support
Classification Name:	Catheter, Percutaneous
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Device Class:	II
510(k) Number	K092299

Reference Devices

Proprietary Name:	TrailBlazer™ Angled Support Catheter
Company Name:	ev3 Inc.
Common Name:	Catheter, Support
Classification Name:	Catheter, Percutaneous
Regulation Number:	21 CFR 870.1250
Product Code:	DQY
Device Class:	II
510(k) Number	K162384

Proprietary Name:	Spectranetics Quick-Cross Extreme Support Catheters
Company Name:	Spectranetics Corp.
Common Name:	Catheter, Support
Classification Name:	Catheter, Percutaneous
Regulation Number:	21 CFR 870.1330
Product Code:	DQY
Device Class:	II
510(k) Number	K082561

Note: Reference devices are only to support the substantial equivalence of the subject device in regards to the angled tip.

5.4 – Device Description

The TXM Support Catheter is an over the wire (OTW) single lumen catheter with atraumatic tapered tip. The distal tip catheter shaft has 6 radiopaque markers (including the tip) that works as an aid to estimate positioning within the vasculature. It consists of a lubricious inner liner made from Teflon, and stainless steel braid over the liner and an outer layer that consists of clear Nylon 12 polymer. One gold marker band is positioned on the proximal side of the tip. A polycarbonate hub is attached to the proximal end of the TXM Support Catheter. The TXM Support Catheter system is offered in 8 models, four with a straight tip and four with an angled tip, and the angled tip configuration has an angle of 30°. All models will have an outer diameter of the 4 French size (0.052") and an inner diameter of 0.039" tapered down to 0.0355" towards the distal tip so that is compatible with a 0.035" guidewires. The device is available in lengths of 65cm, 90cm. 135cm, and 150cm. The catheter is coated with a lubricious hydrophilic coating. The device is supplied sterile and is intended for single use only.

The following table lists the models and sizes available for TXM Support Catheter.

Table 5.4 TXM Support Catheter Models and Sizes

Product Code	French size	Shaft Length (cm)	Outer Diameter (inches)	Inner Diameter (inches)	Marker Band Material	Tip Shape
SC-35065-S	4	65	0.052"	0.039" - 0.0355"	Gold	Straight
SC-35090-S	4	90	0.052"	0.039" - 0.0355"	Gold	Straight
SC-35135-S	4	135	0.052"	0.039" - 0.0355"	Gold	Straight
SC-35150-S	4	150	0.052"	0.039" - 0.0355"	Gold	Straight
SC-35065-A	4	65	0.052"	0.039" - 0.0355"	Gold	Angled
SC-35090-A	4	90	0.052"	0.039" - 0.0355"	Gold	Angled
SC-35135-A	4	135	0.052"	0.039" - 0.0355"	Gold	Angled
SC-35150-A	4	150	0.052"	0.039" - 0.0355"	Gold	Angled

5.5 – Indications for Use

The TXM Support Catheters are percutaneous, single lumen catheters designed for use in the peripheral vascular system. TXM Support Catheters are intended to guide and support a guide wire during access of the vasculature, allow for wire exchanges and provide a conduit for the delivery of saline solutions or diagnostic contrast agents.

The Indications for Use are identical, the devices are both intended for peripheral vascular use and the Indications for Use do not change the intended use of the TXM Support Catheter when compared to the predicate device.

5.6 – Summary of Technological Characteristics Comparison

Based on a comparison of the indications for use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging, it is determined that the TXM Support Catheter is substantially equivalent to the predicate device. Table 5.6 below provides a comparison of the TXM Support Catheter and the predicate.

Table 5.6 Comparison of the TXM Support Catheter and the Predicate Device

Technical Characteristics / Principle of Operation	TXM Support Catheter	TrailBlazer ™ Support Catheter	Substantially Equivalent?
Length	65cm, 90cm, 135 cm,150cm	65cm, 90cm, 135 cm,150cm	Yes
Outer Diameter	0.052”	0.063”	Yes
Inner Diameter	0.039”- 0.0355”	0.042”-0.036”	Yes
Shape	Straight and Angled	Straight	Yes
Inner Liner Material	Polytetrafluoroethylene (PTFE)*	Unknown	Yes
Braid Reinforcement Material	Stainless Steel*	Not Applicable	Yes
Radiopaque Markers	A Gold marked band and radiopaque markers of Nylon 12 loaded with Tungsten.*	Platinum/Iridium	Yes
Outer Shaft Material	Nylon 12*	Unknown	Yes
Luer Material	Polycarbonate*	Unknown	Yes
Luer Connector	Female Luer Connector*	Female Luer Connector	Yes
Anatomical Site Use	Peripheral Vascular system	Peripheral Vascular system	Yes
Delivery to Site	Over-the-wire	Over-the-wire	Yes
Guidewire Compatibility	Maximum 0.035”	Maximum 0.035”	Yes
Packaging	Tyvek Pouch	Tyvek Pouch	Yes
Sterilization	EtO Gas	EtO Gas	Yes

* Denotes a patient-contacting material.

5.7 – Performance Testing Summary

The following bench tests were performed to evaluate the design elements and performance characteristics of the TXM Support Catheter and to demonstrate substantial equivalence to the predicate device. The TXM Support Catheter met the predetermined acceptance criteria. Testing was performed on non-aged devices (T=0) as well as on devices subject to 2 years of accelerated aging (T=2). Tests results show that the TXM Support Catheter is substantially equivalent to the predicate device.

5.7.1- Bench Testing Summary

Table 5.7.1 below provides a summary of the bench testing performed on the TXM Support Catheter.

Table 5.7.1 Bench Testing TXM Support Catheter

Test No.	Test Name	Applicable Standard or Internal Test Method	Test Results	
1	Dimensional And Physical Attributes	Internal Test Method	T=0 T=2	Pass
2	Catheter Compatibility	Internal Test Method	T=0 T=2	Pass
3	Air Leakage	ISO 10555-1	T=0 T=2	Pass
4	Trackability	Internal Test Method	T=0 T=2	Pass
5	Crossability	Internal Test Method	T=0 T=2	Pass
6	Catheter Stiffness	ASTM D747-10	T=0 T=2	Pass
7	Gravity Flow Rate	ISO 10555-1	T=0 T=2	Pass
8	Power Injection for Flow Rate	ISO 10555-1	T=0 T=2	Pass
9	Lubricity of Hydrophilic Coating	Internal Test Method	T=0 T=2	Pass
10	Durability of Hydrophilic Coating	Internal Test Method	T=0 T=2	Pass
11	Liquid Leakage	ISO 10555-1	T=0 T=2	Pass
12	Static Burst Pressure	ISO 10555-1	T=0 T=2	Pass
13	Tensile Strength	ISO 10555-1	T=0 T=2	Pass
14	Radiopacity	ASTM-F640-12	T=0 T=2	Pass
15	Torqueability	Internal Test Method	T=0 T=2	Pass
16	Torque Strength	Internal Test Method	T=0 T=2	Pass

17	Kink Resistance	Internal Test Method	T=0 T=2	Pass
18	Corrosion Resistance	ISO 10555-1	T=0 T=2	Pass
19	Coating Integrity and Particulates	Internal Test Method	T=0 T=2	Pass
20	Packing Integrity (Seal Strength)	ASTM F88 / F88M - 15	T=0 T=2	Pass
21	Packing Integrity (Packing Dye Penetration)	ASTM F1929–15 /F1886-09	T=0 T=2	Pass
22	Shipping and Transit	ISTA 3A	T=0 T=2	Pass
23	Accelerated Aging	ASTM F1980-07	Pass	
24	Female Luer Verification	ISO 594	Pass	

5.7.2 – Biocompatibility Testing Summary

The TXM Support Catheter is classified as an Externally Communicating Device, Circulating Blood, Limited Contact (≤24 hours). Biocompatibility testing was performed in accordance with ISO 10993 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" (2009). Table 5.7.2 below describes the testing performed to determine biocompatibility.

Table 5.7.2. Summary of Biocompatibility Testing for the TXM Support Catheter

Biological Effect	Test	Compliance Standard
Cytotoxicity	L929 MEM ELUTION	ISO10993-5
Irritation	Intracutaneous Injection	ISO10993-10
Sensitization	Kligman Maximization Murine Local Lymph Assay	ISO10993-10
Systemic Toxicity	Systemic Injection	ISO10993-11
Material Mediated Pyrogenicity	Rabbit Pyrogen	USP<151> ISO10993-11
	Limulus Amebocyte Lysate	
Hemocompatibility	Hemolysis Complete (Direct and Indirect)	ISO10993-4
	Complement Activation	ISO10993-4
	Thromboresistance Evaluation *In vivo*	ISO10993-4

5.8 - Sterilization Testing Summary

Table 5.8 Summary of Sterilization Testing

Validation Sterilization Process	Compliance Standard	Sterility Assurance Level (SAL)	Validation Result
Ethylene Oxide Gas	ISO 11135	10^{-6}	Pass

5.9 – Conclusion

The TXM Support Catheter is substantially equivalent in intended use, fundamental design, technology and principles of operation, materials, performance, sterilization, and packaging to the predicate device. Differences between the devices do not raise any new issues of safety or effectiveness.